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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,040	07/17/2001	Josef Endl	BMID9814US	8496

7590

02/09/2004

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 02/09/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,040

Applicant(s)

ENDL ET AL.

Examiner

Bao-Thuy L. Nguyen

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1641

-- Th MAILING DATE of this communication app ars on th cover she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-28 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17 and 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

1. Applicant's amendment filed 11/17/03 has been received. Claims 16, 17 and 22-27 have been withdrawn. Claim 28 has been added. Claims 16-28 are pending.
2. The text of those US codes not found in this office action may be found in a previous office action.

REJECTION WITHDRAWN

Claim Rejections - 35 USC § 112

3. The rejection of claims 18-20 under 35 U.S.C. 112, first paragraph is withdrawn in view of the submission of the biological deposit information.
4. The rejections of claims 18-20 under 35 USC 112, first paragraph as lacking written description is withdrawn in view of Applicant's argument.

Claim Rejections - 35 USC § 102

5. The rejection of claims 18-20 under 35 USC 102(e) as being anticipated by Endl et al (US 5,888,813) is withdrawn in view of the amendment to the claims and the arguments presented by Applicant.
6. The rejection of claims 18-20 under 35 USC 102(b) as being anticipated by Solimena et al is withdrawn in view of the amendment to the claims and the arguments presented by Applicant.

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Claim Rejections - 35 USC § 103

7. The rejection of claims 18-20 under 35 USC 103(a) as being unpatentable over Payton et al in view of Kohler is withdrawn in view of amendment to the claims and the arguments presented by Applicant.

REJECTION MAINTAINED

8. Claims 21 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Endl et al (US 5,888,813).

Endl discloses human monoclonal antibodies of the IgG isotype against human pancreatic islet cells and method for making the same. Endl specifically teaches collecting lymphocytes from prediabetics or newly diagnosed diabetics whose sera show a high serum antibody titer to islet cells were used. See column 6, example 1. Endl teaches isolating mononuclear cells by means of a density gradient, immortalizing the cells, treating the culture supernatant of the immortalized cells with a conjugate of antibodies against human Fcγ and a label, subsequently treating with human immunoglobulin, incubating with immobilized human pancreatic islet cells, identifying an immortalized human cell culture which produces an antibody against pancreatic islet cells via determination of the label bound to the immobilized islet cells, isolating a human immortalized cells which produces this antibody, propagating this immortalized cell and isolating the monoclonal antibody produced by the cells. See column 2, lines 14-28; column 3, lines 1-24.

Response to Arguments

9. Applicant's arguments, filed November 17, 2003, with respect to claims 18-20 have been fully considered and are persuasive. The 112, first paragraph and art rejections of these claims have been withdrawn.

10. The arguments with respect to the 102(e) rejection of claim 21 have been fully considered but they are not persuasive.

Applicant argues that Endl fails to teach the method claim 21 because they do not teach the production of a monoclonal antibody that binds specifically to islet cell antigen, nor do they teach the step of isolating peripheral mononuclear cells from the blood of a human donor having a high serum antibody titer of islet cell antigen.

This argument is not persuasive because Endl specifically teach the isolation of mononuclear cells from diabetic or prediabetic patients whose sera show a high serum antibody titer to islet cells. See column 6, lines 30-67.

Applicant also argues that although the Endl patent discusses human monoclonal antibodies against human pancreatic islet cells, it describes in detail only those monoclonal antibodies that bind to islet cell antigen GAD, thus it fails to teach the claimed invention.

This argument is not persuasive. The claimed invention -- (claims 21 and 28) -- is directed toward a method of making a human monoclonal antibody against islet cell antigen and the monoclonal antibody produced by this method. In addition to teach a method and an antibody to islet cell antigen GAD, Endl also teaches a method and an antibody resulting therefrom to islet cell antigen of the pancreas, as discussed above. Specifically, Endl teaches that they made monoclonal antibodies to both human pancreatic islet cell and islet cell antigen GAD. See column 2.

Allowable Subject Matter

11. Claims 18-20 are allowable.

12. The following is a statement of reasons for the indication of allowable subject matter:

Claims 18-20 define over the prior art of record because the prior art of record fails to teach or make obvious a human monoclonal antibody that binds specifically to islet cell antigen IA-2 in a manner equivalent to an antibody from cell line IA-2, 96-3-1 having deposit number DSM ACC2365. The phrase "in a manner equivalent" means those antibodies in which there is a detectable epitope overlap with the antibody having deposit number DSM ACC2365.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

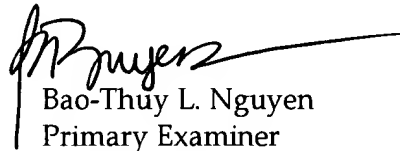
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641

6 February 2004